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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,024	09/12/2005	Rene Bernards	620-378	8133

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EXAMINER	
BOWMAN, AMY HUDSON	
ART UNIT	**PAPER NUMBER**
1635	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/542,024	BERNARDS ET AL.	
	Examiner	Art Unit	
	Amy H. Bowman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19 and 21-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-19 and 21-36* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-4, 6-10 and 13, drawn to an assay method including bringing into contact a putative modulator and a VDU1 polypeptide, further comprising a VHL polypeptide.

Group II, claim 5, drawn to an assay method including bringing into contact a putative modulator with VDU1 and an ubiquitinated VDU1 substrate.

Group III, claims 11 and 12, drawn to an assay method including bringing into contact a putative modulator with a test system comprising VDU1 and ubiquitinated HIF-α.

Group IV, claims 14, 15, 26 and 27, drawn to a modulator of VDU1 for use in a method of medical treatment, wherein the modulator is an antibody against VDU1, and to a composition comprising the modulator and a pharmaceutically acceptable excipient.

Group V, claims 14, 16 and 26, drawn to a modulator of VDU1 for use in a method of medical treatment, wherein the modulator is a nucleic acid encoding VDU1, and to a composition comprising the modulator and a pharmaceutically acceptable excipient.

Group VI, claims 14, 17 and 26, drawn to a modulator of VDU1 for use in a method of medical treatment, wherein VDU1 expression is reduced, wherein the modulator is an antisense RNA, to a vector encoding the modulator, and to a composition comprising the modulator and a pharmaceutically acceptable excipient.

Group VII, claims 14, 17 and 26, drawn to a modulator of VDU1 for use in a method of medical treatment, wherein VDU1 expression is reduced, wherein the modulator is a double stranded VDU1 RNA, to a vector encoding the modulator, and to a composition comprising the modulator and a pharmaceutically acceptable excipient.

Group VIII, claims 14, 17 and 26, drawn to a modulator of VDU1 for use in a method of medical treatment, wherein VDU1 expression is reduced, wherein the modulator is a

ribozyme, to a vector encoding the modulator, and to a composition comprising the modulator and a pharmaceutically acceptable excipient.

Group IX, claims 14, 18 and 26, drawn to a modulator of VDU1 for use in a method of medical treatment, wherein the modulator is a polypeptide having an amino acid sequence corresponding to a portion of the VHL amino acid sequence, and to a composition comprising the modulator and a pharmaceutically acceptable excipient.

Group X, claims 14, 18 and 26, drawn to a modulator of VDU1 for use in a method of medical treatment, wherein the modulator is a polypeptide having an amino acid sequence corresponding to a portion of the VDU1 amino acid sequence, and to a composition comprising the modulator and a pharmaceutically acceptable excipient.

Group XI, claims 19, 21 and 22, drawn to the use of a modulator of VDU1 for the manufacture of a medicament for the treatment of a condition in which modulation of HIF is of therapeutic value, which comprises use of an inhibitor of VDU1. **Election of this group requires further election of one disease from claim 22, as explained below.**

Group XII, claims 19, 23, and 24, drawn to the use of a modulator of VDU1 for the manufacture of a medicament for the treatment of a condition in which modulation of HIF is of therapeutic value, which comprises use of an activator of VDU1. **Election of this group requires further election of one disease from claim 24, as explained below.**

Group XIII, claim 25, drawn to a method of treating a disease in which modulation of HIF is of therapeutic value comprising administering an agent which modulates VDU1 activity.

Group XIV, claims 28 and 29, drawn to a method of treating an individual with cylindromatosis by administering an effective amount of an NF-kB inhibitor, wherein said inhibitor is aspirin.

Group XV, claims 28 and 29, drawn to a method of treating an individual with cylindromatosis by administering an effective amount of an NF-kB inhibitor, wherein said inhibitor is prostaglandin A1.

Group XVI, claims 30 and 31, drawn to the use of an NF-kB inhibitor for the manufacture of a medicament for the treatment of cylindromatosis, wherein said inhibitor is aspirin.

Group XVII, claims 30 and 31, drawn to the use of an NF-kB inhibitor for the manufacture of a medicament for the treatment of cylindromatosis, wherein said inhibitor is prostaglandin A1.

Group XVIII, claim 32, drawn to a method of treating a disease associated with activation of NF-kB comprising administering an agent which increases expression of CYLD.

Group XIX, claim 33, drawn to use of an agent which increases expression of CYLD for the manufacture of a medicament for the treatment of a disease associated with activation of NF-kB.

Group XX, claims 34-36, drawn to an assay comprising providing a cell culture in which CYLD activity is suppressed or missing and bringing the culture into contact with an agent to be assayed and determining the effect of the agent on NF-kB activity, wherein CYLD activity is suppressed by siRNA.

The inventions listed as Groups I-XX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

37 CFR 1.475(b) states:

"An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn **only** to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

37 CFR 1.475(c) states:

"If an application contains claims to more or less than one of the combination of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present."

37 CFR 1.475(d) also states:

"If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first

recited invention of each other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c)."

37 CFR 1.475(e) further states:

"The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternative within a single claim."

In the instant case, the product is not the first claimed invention and therefore there is no unity of invention between the products and processes. Furthermore, the instant claims do not all fall into one of the only 5 combinations of categories which can have unity of invention as defined by 1.475(b). The claims are directed to multiple processes comprising separate and distinct steps, as well as to separate and distinct products that are structurally distinct and act via completely different mechanisms. Therefore, there is no special technical feature linking the groups listed above.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of claim 22 are as follows:

Inflammatory disease, cancer, macular degeneration, diabetic retinopathy, Alzheimer's, atherosclerosis, psoriasis, rheumatoid arthritis, and endometriosis.

The species of claim 24 are as follows:

Peripheral and coronary heart disease and myocardial ischaemia.

Upon election of group XI or XII, applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the diseases have separate and distinct etiologic considerations, each requiring a separate and distinct search.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy H. Bowman whose telephone number is (571) 272-0755. The examiner can normally be reached on Monday-Thursday 6:30 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amy H. Bowman/
Patent Examiner
Art Unit 1635